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2        The opinion in support of the decision being  
3        entered today is not binding precedent of the board.  
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10        Paper 1  
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15        Filed by:  
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18        Fred E. McKelvey  
19        Senior Administrative Patent Judge  
20        Mail Stop Interference  
21        P.O. Box 1450  
22        Alexandria Va 22313-1450  
23        Tel: 571-272-9797  
24        Fax: 571-273-0042  
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30        Filed 23 February 2006  
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30        UNITED STATES PATENT AND TRADEMARK OFFICE  
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30        BEFORE THE BOARD OF PATENT APPEALS  
31        AND INTERFERENCES  
32        (Senior Administrative Patent Judge McKelvey)  
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30        TSUGUNORI NOTOMI and TETSU HASE,  
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30        Junior Party  
31        (Patent 6,410,278 B1),  
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30        ELAZAR RABBANI, JANNIS G. STAVRIANOPOULOS,  
31        JAMES J. DONEGAN, JACK COLEMAN and MARLEEN WALNER,  
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30        Senior Party  
31        (Application 10/306,990).  
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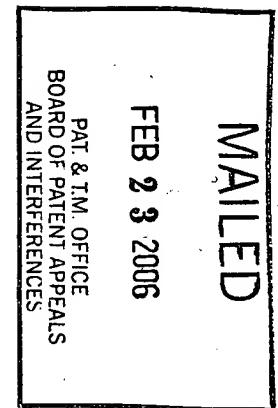
30        Patent Interference 105,427 (McK)  
31        Technology Center 1600  
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30        DECLARATION  
31        37 CFR § 41.203(b)  
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30        Part A.  
31        Declaration of interference  
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30        1. An interference is declared between the above-  
31        identified parties. 35 U.S.C. § 135(a); 37 CFR § 41.203(b).  
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30        2. Details of the application, patent, count and  
31        claims designated as corresponding or as not corresponding to the  
32        count appear in Parts E and F of this DECLARATION.  
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Part B.  
Judge managing the interference

Senior Administrative Patent Judge McKelvey has been designated to manage the interference. 37 CFR § 41.104(a).

**Part C:  
Standing order**

8                   1. A Trial Division STANDING ORDER (3 Jan. 2006)  
9 (Paper 2) accompanies this DECLARATION.  
10               2. The STANDING ORDER applies to this interference,  
11 including the provisions related to Electronic Filing. See  
12               ¶ 105, pages 17-20.

**Part D.**  
**Initial conference call and motions lists**

## Conference call

17                   1. A conference call to discuss the interference is  
18                   set for:  
19                   4:00 p.m. (1600 hours Eastern time) on Friday, 21 April 2006.

4:00 p.m. (1600 hours Eastern time) on Friday, 21 April 2006.

20  
21                   2. The board will initiate the call.

## Motions lists

23                   3. On or before:  
24                   noon (1200 hours Eastern time) Monday, 17 April 2006,  
25                   each party shall file, and on or before:  
26                   5:00 p.m. (1700 hours Eastern time) Monday, 17 April 2006,

1 each party shall serve, a notice stating the relief the party  
2 requests, i.e., a motions list including motions the party seeks  
3 authorization to file. 37 CFR § 41.120(a); STANDING ORDER ¶ 204,  
4 (Paper 2, page 58).

5 4. The default procedure for filing and serving is  
6 motions lists are to be filed before being served.

7 5. By filing before service, one party will not have  
8 access to an opponent's motions list prior to filing the party's  
9 motions list.

10 6. Nevertheless, the parties may mutually agree to  
11 discuss and serve motions lists at any time prior to the date and  
12 time motions lists are due.

13 7. The following shall be included in any motions  
14 list:

15 (1) Proposed motion for benefit must identify the  
16 application(s) for which benefit will be  
17 sought.

18 (2) Proposed motion to attack benefit must  
19 identify the application(s) being attacked.

20 (3) Proposed motion seeking judgment against an  
21 opponent based on alleged unpatentability  
22 must identify the statutory basis for the  
23 alleged unpatentability and:

24 (a) if based on the prior art, identify the  
25 prior art;  
26 (b) if based on the first paragraph of  
27 35 U.S.C. § 112, identify whether

written description, enablement and/or best mode will be the basis of the proposed motion;

- (c) if based on no interference-in-fact, briefly identify the reason;
- (d) if based on an alleged failure to comply with 35 U.S.C. § 135(b), briefly identify the reason;
- (e) if claim correspondence is involved, identify any claim to be designated as corresponding or not corresponding to the count;
- (f) if a new count is to be sought, identify the new count.

8. A motions list shall not contain any "reservation clause" whereby a party attempts to reserve a right to file additional motions. Additional motions are those authorized by the board consistent with the rules.

9. A sample schedule for taking action during the motion phase appears as Form 2 (page 69) in the STANDING ORDER.

10. Counsel are encouraged to discuss the schedule prior to the conference call and to agree, essentially consistent with the sample schedule, on dates for taking action.

11. A typical motion period lasts approximately eight (8) months.

12. Counsel should be prepared to justify any request for a shorter or longer period.

Part E.  
Identification of the parties  
Assignment of exhibit numbers  
Initiating settlement discussions

### Junior Party<sup>1</sup>

Named inventors: Tsugunori Notomi, Japan  
Tetsu Hase, Japan

Patent:<sup>2</sup> U.S. Patent 6,410,278 B1  
issued 25 June 2002  
based on application 09/530,061  
filed 8 November 1999

## Title: Process for synthesizing nucleic acid

Assignee: Eiken Kagaku Kabushiki Kaisha

<sup>1</sup> The junior party is the party with the latest accorded priority date as set out in this DECLARATION. 37 CFR § 41.201 (definition of "Senior party"); 37 CFR § 41.207(a)(1).

<sup>2</sup> The file is a paper file, not an Image File Wrapper (IFW) file. The first maintenance fee was timely paid on 16 December 2005 (see the enclosed USPTO fee records associated with the patent).

### Senior Party<sup>3</sup>

Named inventors:      Elazar Rabbani, New York  
                          Jannis G. Stavrianopoulos, New York  
                          James J. Donegan, New York  
                          Jack Coleman, New York  
                          Marleen Walner, New York

Application:<sup>4</sup>      Application 10/306,990,  
                          filed 29 November 2002

Title:                   Novel methods for amplifying and  
                          detecting nucleic acid sequences

Assignee:                Enzo Life Sciences, Inc.  
                          Enzo Biochem, Inc.

<sup>3</sup> The senior party is the party with the earliest accorded priority date as set out in this DECLARATION. 37 CFR § 41.201 (definition of "Senior party"); 37 CFR § 41.207(a)(1).

The file is an Image File Wrapper (IFW), not a paper file.

**Assignment of exhibit numbers  
37 CFR § 41.154(c)(1)**

1. The senior party [Rabbani] is assigned exhibit

1001-1999

2. The junior party [Notomi] is assigned exhibit

2001-2999

3. If necessary, the board will use exhibit numbers:

3001-3999

Initiating settlement discussions  
STANDING ORDER ¶ 126.1 (Paper 2, pages 40-41)

4. The senior party is responsible for initiating  
discussions.

Part F.  
Count and claims of the parties

### Count 1

A method comprising:

- (A) providing a template having
  - (i) a 3' end portion comprising a first region located 3' terminal and a first complementary region which, under suitable conditions, anneal to one another to form a first loop,
  - (ii) a 5' end portion comprising a second region located 5' terminal and a second complementary region which, under suitable conditions, anneal to one another to form a second loop, and
  - (iii) a region connecting the 3' end portion and the 5' end portion;
- (B) extending the 3' terminal of the template to the 5' end of the template by means of a polymerase having strand displacement activity, when the first region and first complementary region are annealed to one another to form the first loop, to form a template extension which includes a third region located 3' terminal and a third complementary region that are substantially the same as the second complementary region and second region, respectively, and which, under suitable conditions, anneal to one another to form a third loop;
- (C) annealing to the first loop of the extended template an oligonucleotide primer comprising at the 3' terminal a nucleotide sequence complementary to at least a part of the first loop and at the 5' terminal a nucleotide sequence complementary to the first region of the template;



1           The claims of the parties are:

2           Notomi:           1-19

3           Rabbani:          216

4           The claims of the parties which correspond to Count 1 are:

5           Notomi:           11

6           Rabbani:          216

7           The claims of the parties which do not correspond to Count 1

8           are:<sup>5</sup>

9           Notomi:           1-10 and 12-19

10          Rabbani:          None

11          The parties are accorded the following priority benefit for

12          Count 1:

13          Notomi:<sup>6</sup>          None

14          Rabbani:           U.S. Patent 6,764,821<sup>7</sup>  
15                            issued 20 July 2004  
16                            based on application 09/439,594  
17                            filed 12 November 1999

18          U.S. Patent 6,743,605<sup>8</sup>  
19                            issued 01 June 2004  
20                            based on application 09/104,067  
21                            filed 24 June 1998

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<sup>5</sup> A claim which does not correspond to any count is not involved in the interference within the meaning of 35 U.S.C. § 135(a).

<sup>6</sup> See Paper 4 for a discussion of possible benefit for Notomi.

<sup>7</sup> The file is an Image File Wrapper (IFW), not a paper file.

<sup>8</sup> The file is a paper file, not an Image File Wrapper (IFW) file.

Part G.  
Heading to be used on papers

The following heading must be used on all papers filed in this interference. STANDING ORDER ¶ 106.1.1 (Paper 2, page 20).

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES  
(Senior Administrative Patent Judge McKelvey)

TSUGUNORI NOTOMI and TETSU HASE,

Junior Party  
(Patent 6,410,278 B1)  
(Patent 6,974,670 B2),

v.

ELAZAR RABBANI, JANNIS G. STAVRIANOPoulos,  
JAMES J. DONEGAN, JACK COLEMAN and MARLEEN WALNER,

Senior Party  
(Application 10/306,990).

Consolidated Interferences  
Patent Interference 105,427 (McK)  
Patent Interference 105,432 (McK)  
Technology Center 1600

**Part H.**  
**Order form for requesting file copies**

1. When requesting copies of files, a party shall use STANDING ORDER Form 4 (page 71).

2. Use of Form 4 will expedite processing of any request.

3. A party should attach to any request for file copies a photocopy of Part E of this DECLARATION with a hand-drawn circle around the patents and applications for which a copy of a file wrapper is requested.

4. The parties are advised that a single order for files may be filled by the Office of Public Records at more than one time, particularly in a case like the present case where both IFW and paper files are involved. STANDING ORDER ¶ 109.2 (Paper 2, pages 25-27).

**Part I.**  
**Required paragraph for affidavits and declarations**

1. The board has experienced cases in which a witness has belatedly advanced reasons why the witness would be unable to appear for cross examination at a reasonable time and place in the United States.

2. Consequently, to prevent surprise and hardship to the party relying on the testimony of the witness, the following paragraph must be included on the signature page of all affidavits (including declarations) filed in this case .

STANDING ORDER ¶ 157.2 (Paper 2, pages 52-53):

In signing this affidavit (declaration), I understand that the affidavit (declaration) will be filed as evidence in a contested case before the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office. I also acknowledge that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the time allotted for cross examination.

/ss/Fred E. McKelvey  
FRED E. MCKELVEY,  
Senior Administrative Patent Judge<sup>9</sup>

23 February 2006  
Entered at: Alexandria, VA

As part of board efforts under the government Paperwork Elimination Act, signatures on papers originating from the board have been phased out in favor of a completely electronic record. Consequently, in this case papers originating at the board will not have signatures. The signature requirements for the parties have not changed. See, e.g., 37 CFR § 10.18 (2005).

1 Enc (there is no Form PTO-850):  
2

3 STANDING ORDER (3 Jan. 2006) (Paper 2)  
4 ORDER CONSOLIDATING INTERFERENCES (Paper 3)  
5 ORDER DISCUSSING COUNT AND NOTOMI BENEFIT (Paper 4)  
6 NOTICE OF REQUEST FOR ASSISTANCE ON TECHNOLOGY  
7 and ORDER (Paper 5)  
8 ORDER CANCELLING CLAIMS FROM RABBANI APPLICATION (Paper 6)  
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10 The following additional documents (1) are provided to  
11 permit the parties to gain an early appreciation of the nature of  
12 the interference and (2) do not constitute complete copies of any  
13 file. They are not part of the record of the interference and  
14 cannot be relied upon in the future merely because they are  
15 enclosed with this DECLARATION. If a party would like any of the  
16 following documents considered in the interference, the party  
17 should make the document an exhibit and offer the exhibit in  
18 evidence.  
19

20 Copy U.S. Patent 6,410,278 B1  
21 Copy U.S. Patent 6,974,670 B2  
22 Copy of claims of application 10/306,990 before cancellation  
23 of Rabbani claims 146-215, 217-234 and 238-274  
24 Copy of USPTO maintenance fee payment  
25 U.S. Patent 6,410,278 B1  
26 Bibliographic data

1 cc (via overnight delivery):  
2  
3 Attorney for Notomi  
4 (real party in interest  
5 Eiken Kagaku Kabushiki Kaisha):  
6  
7 Michael L. Goldman, Esq  
8 NIXON PEABODY LLP  
9 Clinton Square  
10 Corner of Clinton Avenue and Broad Street  
11 Rochester, NY 14603-1051  
12  
13 Tel: 716-263-1000 (main)  
14 Fax: 716-263-1800  
15 Email: None  
16  
17 Attorney for Rabbani  
18 (real party in interest  
19 Enzo Life Sciences, Inc. and  
20 Enzo Biochem, Inc.):  
21  
22 Ronald C. Fedus, Esq.  
23 ENZO BIOCHEM, INC.  
24 527 Madison Avenue (9th Floor)  
25 New York, NY 10022  
26  
27 Tel: 212-583-0100  
28 Fax: 212-583-1050  
29 Email: None

## INTERFERENCE DIGEST

Interference No. 105,427

Paper No. 22

Name: Tsugunori Notomi, et al.

Serial No.: 09/530,061

Patent No. 6,410,278, granted 06/25/02

Title: Process for synthesizing nucleic acid

Filed: 09/01/00

Interference with Rabbani et al.

### DECISION ON MOTIONS

Administrative Patent Judge, \_\_\_\_\_ Dated, \_\_\_\_\_

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### FINAL DECISION

Board of Patent Appeals and Interferences, \_\_\_\_\_ Dated, \_\_\_\_\_

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Court, \_\_\_\_\_ Dated, \_\_\_\_\_

### REMARKS

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This should be placed in each application or patent involved in interference in addition to the interference letters.